

## **REMARKS**

Claims 1-8, 10-54, and 56-68 are pending in this application. By this Amendment, claims 9 and 55 are canceled without prejudice or disclaimer, and claims 1, 10-13, 20, 29, 34, 47, 56, 57, 59, and 60 are amended.

As an initial matter, Applicant respectfully notes that the Office Action lacks a clear indication of the status of claim 37. Although the claim is indicated as being rejected in the Office Action Summary, that claim was not subject to any rejection in the Detailed Action section of the Office Action. Thus, Applicant presumes that claim 37 contains allowable subject matter. If, however, the Office intended a rejection of that claim, Applicant respectfully requests that the Office set forth a detailed explanation of the basis for that rejection and make any subsequent Office Action non-final to provide Applicant with a full and fair opportunity to respond.

For the following reasons, Applicant respectfully requests reconsideration and withdrawal of all the rejections outstanding in the December 3, 2004 Office Action.

### **35 U.S.C. § 102(b) Rejection**

Claims 1, 3, 8, 28, 47-50, 54, and 58 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,162,209 to Gobron et al. ("Gobron"). Applicant respectfully requests reconsideration and withdrawal of this rejection

#### **Independent Claim 1**

Although Applicant does not necessarily agree with this rejection, Applicant notes that the subject matter recited in now-canceled claim 9 (i.e., the distal member configured to substantially close the lumen) is not subject to this rejection. Accordingly, Applicant amended independent claim 1 to include the subject matter of claim 9. Thus,

reconsideration and withdrawal of this rejection with respect to claims 1, 3, 8, and 28 is respectfully requested.

*Independent Claim 47*

Although Applicant does not necessarily agree with this rejection, Applicant notes that the subject matter recited in now-canceled claim 55 (i.e., a nozzle member configured to substantially seal a distal end of the lumen, the nozzle member defining a flow path in fluid communication between the lumen and an outside of the lumen when the distal end of the lumen is sealed with the nozzle member) is not subject to this rejection. Accordingly, Applicant amended independent claim 47 to include the subject matter of claim 55. Thus, reconsideration and withdrawal of this rejection with respect to claims 47-50, 54, and 58 is respectfully requested.

**35 U.S.C. § 103(a) Rejection Based on Gobron and McGuckin**

Claims 2, 14, 15, 34-36, 38-40, and 43-46 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Gobron in view of U.S. Patent No. 6,589,252 to McGuckin, Jr. ("McGuckin"). Applicant respectfully requests reconsideration and withdrawal of this rejection.

*Dependent Claims 2, 14, and 15*

Applicant notes that claim 9 is not subject to this rejection. As discussed above, independent claim 1 is amended to include the subject matter of now-canceled claim 9. Therefore, independent claim 1 patentably distinguishes from the asserted combination of Gobron and McGuckin. Since dependent claims 2, 14, and 15 depend directly or indirectly from independent claim 1, those claims should also patentably distinguish

from the asserted combination of Gobron and McGuckin. Applicant respectfully requests reconsideration and withdrawal of this ground of rejection.

*Independent Claim 34*

Independent claim 34 recites a medical device comprising, among other things, “an elongated member having ... a lumen” and “a nozzle member configured to substantially seal the distal end of the lumen, the nozzle member defining a flow path in fluid communication between the lumen and an outside of the elongated member when the distal end of the lumen is sealed with the nozzle member.” As detailed below, neither Gobron nor McGuckin, either taken alone or in combination, teaches or suggests the subject matter of claim 34.

As discussed above, in the 35 U.S.C. § 102(b) rejection based on Gobron, the Office Action implies that Gobron does not disclose, among other things, “a distal member configured to substantially close the lumen” (i.e., the subject matter of original claim 9). Despite a similar recitation of “a nozzle member configured to substantially close the lumen” in claim 34, the Office Action rejects claim 34 without specifically pointing out where in Gobron or McGuckin there is any teaching or suggestion of the recited “nozzle member.” The Office Action relies on McGuckin only for its alleged teachings of a distal member “having a smaller cross-sectional flow area than that of the lumen” and “a connector for receiving cautery current,” but does not rely on McGuckin for any teaching of a nozzle member to substantially close the lumen.

In fact, McGuckin does not disclose, or otherwise suggest, among other things, “a nozzle member configured to substantially close the lumen,” as recited in claim 34. For example, McGuckin discloses a surgical apparatus for excision of percutaneous

breast tissue. The apparatus includes an inner rotatable shaft 20, a piercing member 65, and a plurality of flexible electrocautery cutting blades 50 extending between the shaft 20 and the piercing member 65. The shaft 20 of McGuckin includes an interior channel 21 extending forwardly through the center of the cutting blades 50 and connecting with a dye port 70 of the piercing membrane 65. See, e.g., Figs. 3 and 4, and col. 6, lines 50-65, of McGuckin. The Office Action appears to assert that the interior channel 21 or the shaft 20 corresponds to the recited "elongated member." However, nowhere in McGuckin is there any teaching or suggestion of a distal member that is configured to substantially seal the distal end of the channel 21 or the shaft 20. Therefore, McGuckin does not disclose "a nozzle member configured to substantially seal the distal end of the lumen," as recited in claim 34.

For at least these reasons, independent claim 34 patentably distinguishes from the asserted combination of Gobron and McGuckin. Dependent claims 35, 36, 38-40, and 43-46, depending directly or indirectly from claim 34, also patentably distinguish at least by virtue of their dependencies from claim 34. Thus, Applicant respectfully requests reconsideration and withdrawal of this ground of rejection.

Worth noting is that, contrary to the Office Action's assertion, McGuckin also does not disclose a distal member having a cross-sectional flow area less than a cross-sectional flow area of the lumen, as recited in claims 2 and 35. Instead, McGuckin merely discloses an interior channel 21 connecting to a dye port 70 of the piercing member 65, without any express or inherent disclosure for their sizes or shapes with respect to each other. That is, McGuckin does not disclose, or otherwise suggest, that

a cross-sectional flow area of the dye port 70 is less than a cross-section of the interior channel 21.

Nevertheless, the Office Action appears to rely on Fig. 2 (and possibly Figs. 3 and 4) for its allegation that a cross-sectional flow area of the dye port 70 is smaller than a cross-sectional flow area of the interior channel 21. Fig. 2, however, does not support this allegation because, among other reasons, Fig. 2 does not show any interior channel 21 much less indicate the cross-sectional flow area of the interior channel 21 relative to the dye port 70. Figs. 3 and 4 illustrating different embodiments from Fig. 2 and from one another (see col. 4, lines 30-40, of McGuckin), also do not show the sizes of the dye port 70 and the interior channel 21 relative to each other. That is, no embodiment shown in the figures of McGuckin shows the relative cross-sectional flow areas of the dye port 70 and the interior channel 21, much less suggests that a cross-sectional flow area of the dye port 70 is smaller than a cross-sectional flow area of the interior channel 21. The test of McGuckin similarly lacks any such disclosures.

The Office Action's characterization of McGuckin appears to be based on impermissible hindsight gleaned from the present application. When McGuckin is viewed without such hindsight, there is no express or inherent teaching that a cross-sectional flow area of the dye port 70 is smaller than a cross-sectional flow area of the interior channel 21. Therefore, McGuckin also does not teach the subject matter of claims 2 and 35.

### **35 U.S.C. § 103(a) Rejection Based on Gobron, McGuckin, and Holsinger**

Claims 41, 42, 59, 60, and 62-68 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Gobron in view of McGuckin, and further in view of U.S. Patent No.

5,947,978 to Holsinger ("Holsinger"). Applicant respectfully requests reconsideration and withdrawal of this rejection.

Holsinger discloses a surgical combination apparatus 10 including a first instrument 12 (e.g., an injection needle), a second instrument 14 (e.g., a snare), and a catheter 16 for sheathing the first and second instruments 12, 14. The apparatus 10 includes an actuator 18 and an enlarged proximal end 30 fixedly secured to the actuator 18. The actuator 18 includes a rigid support assembly 40, a slider assembly 44, and a rail assembly 50. See, e.g., col. 4, lines 44-60, and col. 5, lines 8-16, of Holsinger.

*Dependent claims 41 and 42*

While admitting that Gobron and McGuckin do not disclose the recited "nozzle member" that connects to the proximal end of the end effector and that is fixedly connected to a distal end of the elongated member, the Office Action appears to assert that the support assembly 40 and the proximal end 30 of Holsinger correspond to the recited elongated member and nozzle member, respectively. The Office Action then asserts that "[i]t would have been obvious ... to fixedly secure the distal member in the apparatus of McGuckin et al. in order to prevent objects and fluids from entering the lumen, as taught by Holsinger." Applicant respectfully disagrees.

Independent claim 34, as amended, recites "an elongated member being sufficiently flexible to traverse through a tortuous anatomy of a patient's body." The support assembly 40 of the actuator 18, however, is a rigid structure, as discussed above, and therefore is not sufficiently flexible to traverse through a tortuous anatomy of a patient's body. The only element in Holsinger that may arguably be construed as corresponding to the recited "elongated member" is a sheath 16, but there is nothing in

the device of Holsinger that is configured to seal a distal end of the sheath 16.

Therefore, Holsinger does not teach or suggest a nozzle member configured to substantially seal the distal end of the lumen of the elongated member, as recited in claim 34.

#### Independent Claim 59

Independent claim 59, as amended, recites, among other things, “an elongated member having ... a distal end ... extending into the patient.” The support member 40 of the actuator 18 in Holsinger, however, cannot correspond to the recited “elongated member” because its distal end does not extend into a patient. As discussed above, the only element in Holsinger that may arguably be construed as corresponding to the recited “elongated member” is a sheath 16, and there is nothing in the device of Holsinger that is configured to seal a distal end of the sheath 16. Therefore, Holsinger does not teach the recited distal member that is “configured to substantially seal the distal end of the lumen,” as recited in claim 59.

At least for this reason, independent claim 59 patentably distinguishes from the asserted combination of Gobron, McGuckin, and Holsinger. Dependent claims 60 and 62-68, depending directly or indirectly from claim 59, also patentably distinguish at least by virtue of their dependency from claim 59.

#### Other 35 U.S.C. § 103(a) Rejections

Claims 4-7, 9-13, 16-27, 29-33, 51-53, 55-57, and 61 are rejected under 35 U.S.C. § 103(a) as being unpatentable over two or more of Gobron; McGuckin; Holsinger; U.S. Patent No. 5,599,324 to McAlister et al. (“McAlister”); U.S. Patent

5,176,688 to Narayan et al. ("Narayan"); U.S. Patent No. 5,575,694 to Hawkins et al. ("Hawkins").

As discussed above, each of independent claims 1, 34, 47, and 59 patentably distinguish from Gobron, McGuckin, and Holsinger. None of the other cited secondary references, i.e., McAlister, Naraya, and Hawkins, supplies the deficiencies of Gobron, McGuckin, and Holsinger. For example, none of McAlister, Naraya, and Hawkins discloses, among other things, the recited nozzle member or distal member.

Thus, claims 4-7, 9-13, 16-27, 29-33, 51-53, 55-57, and 61 also patentably distinguish from the cited references at least by virtue of their respective dependencies from independent claims 1, 34, 47, or 59.

Applicant respectfully requests the reconsideration of this application, the withdrawal of all the outstanding rejections, and the allowance of all pending claims.

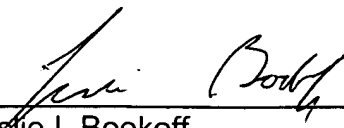
The Office Action contains a number of statements and characterizations regarding the claims and the related art. Applicant declines to necessarily subscribe to any statement or characterization in the Office Action, regardless of whether it is addressed above.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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